IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT
ON PROXIMATE CAUSATION GROUNDS

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INTRODUCTION

Under settled West Virginia law, Plaintiffs cannot recover against Defendants[1] by proving only that they were injured as a result of the opioid crisis. Nor is it enough for Plaintiffs to establish that Defendants had inadequate suspicious-order monitoring systems (they did not) or failed to halt shipment of particular pharmacy orders. To succeed on their claims, Plaintiffs also must prove proximate causation—that is, a ***direct*** connection between Defendants' alleged wrongdoing and Plaintiffs' alleged injuries. The discovery record confirms that they cannot meet that burden for two independent reasons.

1. ***Plaintiffs' alleged injuries are too remote as a matter of law***. As a matter of well-settled West Virginia law, proximate causation does not exist (and summary judgment is required) when the evidence shows that independent actors stand between the defendant's alleged misconduct and the plaintiff's alleged injury. Here, the record demonstrates that the FDA-approved opioid medications that Defendants shipped to state-licensed customers would have sat on a pharmacy shelf, reaching no one and causing no harm, but for the independent actions of two different medical professionals: (1) the doctor who prescribed the medications and (2) the pharmacist who dispensed them pursuant to a legitimate prescription. Moreover, with respect to any harm caused by diversion of prescription opioids, the record shows that two additional acts, ***both illegal***, must have occurred: (1) the opioid must have been diverted to illegal use; and (2) someone must have illegally possessed and used the diverted opioid. Only after these four steps—prescribing, dispensing, illegal diversion and illicit use—might Plaintiffs suffer harm as a result of the end-user's criminal activity, addiction or overdose. Because in every instance multiple independent actors stand between Defendants' alleged misconduct and Plaintiffs' alleged

[1] AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation.

injuries, Plaintiffs cannot prove the requisite "direct" connection, and Defendants are entitled to summary judgment.

2. *Plaintiffs have no evidence that Defendants' conduct proximately caused any harm*. Defendants are entitled to summary judgment on proximate causation grounds for a second, independent reason: Plaintiffs have no evidence tying specific shipments of opioids into Cabell County to Defendants' alleged wrongdoing, on the one hand, and Plaintiffs' alleged injuries, on the other hand. While Plaintiffs purport to fill this evidentiary gap with expert testimony, they have no expert who testifies that Plaintiffs were harmed by any particular order or group of orders that should have been flagged and halted as "suspicious" under the then-prevailing standard of care. Nor do Plaintiffs have any evidence that Defendants were the cause—let alone a direct cause—of expenses incurred as a result of the use of illegal street drugs such as heroin and illicit fentanyl that are distributed not by Defendants but by drug cartels.

STANDARD OF REVIEW

To survive summary judgment, Plaintiffs may not rest upon "[c]onclusory or speculative allegations." *Hodgin v. UTC Fire & Sec. Americas Corp.*, 885 F.3d 243, 252 (4th Cir. 2018). Instead, they must come forward with "specific facts showing that there is a genuine issue for trial." *Humphreys & Partners Architects, L.P. v. Lessard Design, Inc.*, 790 F.3d 532, 540 (4th Cir. 2015); *see also* Fed. R. Civ. P. 56(c)(1) ("A party asserting that a fact cannot be or is genuinely disputed must support the assertion by … citing to particular parts of materials in the record[.]").

The moving party need not prove the absence of a genuine issue of material fact, but may instead discharge its burden by pointing out the absence of evidence to support the nonmovant's case. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). "The mere existence of a scintilla of evidence" in support of the nonmoving party's position is insufficient to defeat summary

judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986); *see also CTB, Inc. v. Hog Slat, Inc.*, 954 F.3d 647, 658 (4th Cir. 2020) (same).

ARGUMENT

I. PLAINTIFFS' INJURIES ARE IMPERMISSIBLY REMOTE FROM DEFENDANTS' ALLEGED WRONGDOING AND DEPEND ON THIRD-PARTY CRIMINAL CONDUCT.

It is well-established that "remoteness is a component of proximate cause, which in turn embraces the concept that the judicial remedy cannot encompass every conceivable harm that can be traced to alleged wrongdoing." *Aikens v. Debow*, 208 W. Va. 486, 492 (2000).[2]

To avoid survive summary judgment on proximate causation, Plaintiffs must come forward with evidence of a "***direct relation*** between the injury asserted and the injurious conduct alleged." *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992).[3] This requirement applies to Plaintiffs' public nuisance claims. *See Employer Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W. Va. 2013) (applying the *Holmes* standard to West Virginia state law claims); *see also City of Charleston v. Joint Comm'n*, 2020 WL 4116952, at *22 (S.D. W. Va. July 20, 2020) ("courts have applied the principles of remoteness to state law tort claims insofar as proximate cause requires carefully

[2] *See also, e.g.*, *Humphrey v. Westchester Ltd. P'ship*, 2019 WL 2185972, at *7 (W. Va. May 21, 2019) (affirming grant of summary judgment on proximate causation grounds where alleged injuries "were [too] remote in time and [too] remote from any alleged acts or omissions on the part of [defendant]"); *Metro v. Smith*, 146 W.Va. 983, 124 S.E.2d 460, 464 (1962) ("[T]he negligence which renders a defendant liable for damages must be a proximate, not a remote, cause of injury ..."); *Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1305 (2017) ("It is a well established principle of the common law that in all cases of loss, we are to attribute it to the proximate cause, and not to any remote cause."); *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992) ("[A]mong the many shapes … [proximate cause] took at common law … was a demand for some direct relation between the injury asserted and the injurious conduct alleged.").

[3] *See also* 65 C.J.S. Negligence § 198 ("To plead a direct injury is a key requirement for establishing proximate causation, independent of and in addition to the other traditional elements of proximate cause.")

drawing a line so as to distinguish the ***direct consequences*** in a close causal chain from more attenuated effects influenced by too many intervening causes").

In assessing whether there is a "direct relation" between claimed injuries and conduct, "[t]he general tendency of the law … is not to go beyond the first step" in the causal chain. *Holmes*, 503 U.S. at 271–72; *see also Slay's Restoration, LLC v. Wright Nat'l Flood Ins. Co.*, 884 F.3d 489, 494 (4th Cir. 2018) (no "direct relation" when plaintiff relies on "a chain of causation that extends significantly beyond 'the first step'"). A link that is "too remote" or "purely contingent" will not suffice. *Holmes*, 503 U.S. at 271. Thus, it is well-settled that summary judgment is required where the evidence shows that "a vast array of intervening events, including the 'independent medical judgment' of doctors," stands between the alleged misconduct and the alleged injury. *Bristol Myers Squibb Co.*, 969 F. Supp. 2d at 475; *see also City of Charleston*, 2020 WL 4116952, at *26 ("[D]efendants' actions are too attenuated and influenced by too many intervening causes, including the criminal actions of third parties, to stand as the proximate cause of plaintiffs' injuries.") Because liability does not attach absent a finding of proximate cause, summary judgment is required regardless of the requested form of relief.

Plaintiffs contend that Defendants failed to adequately monitor and report to regulators "suspicious orders," which allegedly resulted in "excessive distribution[s]" of opioid medicines into Cabell County. Third Amend. Compl. ¶¶ 801–03, 805, 823, 862. But the record demonstrates that Defendants' alleged misconduct, even if it could be proved, was not the proximate or "direct" cause of Plaintiffs' alleged injuries.

At least ***four independent actions***—including two exercises of professional judgment and two crimes—had to occur before Huntington or Cabell County could be harmed by Defendants' allegedly "excessive distribution[s]" of prescription opioids:

1. Prescribing: Defendants cannot and do not diagnose, treat, or prescribe for patients.[4] That is the job of a licensed, registered physician who is empowered to exercise medical judgment.[5] Defendants have no ability to review or second-guess the validity of any prescription written by a physician,[6] and no opioids can leave a pharmacy shelf lawfully without a prescription.[7]

2. Dispensing: Defendants cannot and do not dispense opioid products to patients.[8] That is the job of a licensed, registered pharmacist, who must operate in compliance with his/her own professional and regulatory duties not to fill illegitimate prescriptions. *See* 21 C.F.R. 1306.04(a), 1306.11.

3. Diversion: The FDA-approved medicines delivered by Defendants to state-licensed pharmacies must be diverted to the illicit market—most often, according to Plaintiffs' experts, by the patient to whom the medicines legitimately were prescribed.[9] That act of diversion is inherently unlawful[10] and necessarily takes place ***after*** the drugs have left the

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[4] *See, e.g.*, Ex. 2 (Painter Dep.) at 21:7–9 ("Q. Can prescription drug distributors write a prescription? A. No."); Ex. 3 (Fioravante Dep.) at 56:12–57:1 ("Q. Are you aware of whether a wholesale distributor has the opportunity to evaluate a patient to determine whether opioids should be prescribed or not? A. I can't see how they would have that ability.").

[5] *See* 21 C.F.R. 1306.04(a); *see also, e.g.*, Ex. 4 (Adkins Dep.) at 67:7–12; Ex. 5 (Kilkenny Dep.) at 86:20–23; Ex. 6 (Mock Dep.) at 24:6–9; Ex. 7 (Shepard Dep.) at 65:5–9; Ex. 8 (Napier Dep.) at 50:5–11.

[6] *See, e.g.*, Ex. 5 (Kilkenny Dep.) at 87:22–88:2 (Physician Director of the Cabell-Huntington Health Department agreeing that distributors should not be making prescribing decisions for individual patients); Ex. 6 (Mock Dep.) at 24:10–25:13 (Chief Medical Examiner for the State of West Virginia testifying that oversight of doctors' prescribing decisions should be "very limited" and does not include distributors); *see also* Ex. 9 (71 Fed. Reg. 52,716) at 52,723 ("[E]ach patient's situation is unique" and prescribing should be "based on the physician's sound medical judgment").

[7] Ex. 10 (Keyes Dep.) at 115:16–116:6 (testifying that pills can only leave a pharmacy through a prescription written by a doctor or illegal means such as illegal sale or theft).

[8] *See, e.g.*, Ex. 11 (Cavacini MDL Dep.) at 267:11–15.

[9] *See* Ex. 12 (Keyes Rep.) at 23 (opining that "[r]eceipt of prescription opioids from a friend or family member is a common mechanism," and noting that more than 50% of non-medical opioid users report having obtained opioids from a friend or relative); Ex. 13 (Lembke Rep.) at 153 ("Among individuals who misuse prescription opioids, the most common source of opioids was pills from family members and friends."); Ex. 14 (Ciccarone Rep.) at 34 (same).

[10] *See, e.g.*, Ex. 15 (Cox. Dep.) at 47:10–13 ("Q. So is it your understanding then that diversion of pharmaceutical drugs is always illegal? A. Yes. Q. So then the person who diverts a pharmaceutical drug has committed a crime, correct? A. Yes."); Ex. 16 (Dial Dep.) at 24:1–5 ("Q. Okay. So in what circumstances would diversion not be criminal? A. I think with an opioid, every circumstance that I've known where they diverted it, it was illegal."); Ex. 17 (Brown Dep.)

pharmacy shelves and are no longer under Defendants' control. There is overwhelming evidence that third parties in Huntington and Cabell County illegally diverted opioids.

4. Illicit Use: No harm can occur absent the use of a diverted prescription opioid. The possession and use of diverted pills without medical authority or a legitimate prescription is a criminal act.[11]

These four actions stand between Defendants' distributions to their DEA-registered customers and any harm to Plaintiffs. Only after these actions all occur are Plaintiffs even in a position to be harmed by diverted prescription opioids, and only then if they happened to incur expense as a result of the end-user's criminal activity, addiction, or overdose.

A recent decision in an opioid-related lawsuit illustrates why Plaintiffs' causation theory fails under West Virginia law. In *City of Charleston v. Joint Commission*, the plaintiff municipalities—including the City of Huntington—sued the body that accredits hospitals nationwide, alleging that its requirement that hospitals treat pain as "The Fifth 'Vital Sign'" and its issuance of opioid-friendly "Pain Management Standards" led to "inappropriate provision of opioids," 2020 WL 4116952, at **3, 4, which in turn caused the municipalities to incur increased health care costs and other injuries similar to the ones alleged in this case.[12] Faced with those allegations, the court held that the municipalities' state-law claims failed the *Holmes* direct injury

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at 15:9–10 ("Q. Okay. And is diversion a crime? A. Yes, it is."); Ex. 18 (Holbrook Dep.) at 42:24–43:1 ("Q. Is there any form of diversion that is not a crime, as far as you know? A. I can't think of one."); *see also* 21 U.S.C. § 841(a) (prohibiting the distribution of any controlled substance except as authorized by the CSA).

[11] *See, e.g.*, Ex. 15 (Cox. Dep.) at 47:22–48:3 ("Q. Just so there's no confusion, use or possession of a diverted pharmaceutical drug is a crime, correct? A. Yes.").

[12] *See id.* at *12 (noting that plaintiffs alleged to have suffered "significant economic damages, including, but not limited to, increased health care costs, insurance and self-insurance costs, health services costs, costs related to responding to and dealing with opioid-related crimes and emergencies, additional first responders, first responder and building department overtime, remediation of dilapidated and fire-damaged properties, criminal vagrancy, and other significant public safety costs and disruptions to quality of life and commerce").

test "given the numerous intervening events and parties standing between" defendant's misconduct and the municipalities' alleged injuries. *Id.* at *25 (applying West Virginia law); *see also id.* at *26 ("In sum, defendants' actions are too attenuated and influenced by too many intervening causes, including the criminal actions of third parties, to stand as the proximate cause of plaintiffs' injuries."). In particular, this Court concluded that the following factors precluded a finding of proximate causation:

- "The independent medical judgment of the prescribing physicians further breaks the chain of causation because, compared to the opioid manufacturers, defendants are one substantial step further removed from the individual patients and from the Municipalities." *Id.* at *25.
- "Even if physicians followed the P[ain]M[anagement] Standards and assessed pain in all patients, no injury would occur unless the physician proceeded to unnecessarily prescribe opioid treatments or if patients obtained the drugs through some other illegal means." *Id.*
- "Plaintiffs' claims rely on various criminal actions of third parties, such as illegal drug trafficking, criminal vagrancy, stolen merchandise, and property crimes, as triggering a need for increased governmental services and remediation." *Id.*

Like the defendant in *City of Charleston*—which did not make prescription opioids available to end-users but rather issued "Pain Management Standards" that allegedly influenced prescribing practices, *id.* at *3—Defendants did not sell opioid medications to Cabell County residents but only to DEA-registered dispensaries. As in *City of Charleston*, but for "[t]he independent medical judgment of the prescribing physician[]" and dispensing pharmacist, the prescription medicines delivered by Defendants to state-licensed pharmacies would not ever reach patients and "no injury would occur." *Id.* at *25. Also as in *City of Charleston*, where the plaintiff municipalities' harm was directly caused not by the defendant but by the "criminal actions of third parties," *id*., Plaintiffs' alleged harm was directly caused by (i) the patients or others who diverted lawfully prescribed controlled substances to illegal use, and (ii) those individuals in Cabell County who used the medicines unlawfully. Thus, just as in *City of Charleston*, "defendants' actions are

too attenuated and influenced by too many intervening causes, including the criminal actions of third parties, to stand as the proximate cause of plaintiffs' injuries." *Id.* at *26.[13]

The court responsible for the coordinated opioid litigation in Connecticut also applied the *Holmes* "direct relation" test to dismiss opioid-related nuisance claims brought against wholesale distributors by various Connecticut municipalities. *See City of New Haven v. Purdue Pharma, L.P.*, 2019 WL 423990 at *3 (Conn. Super. Ct. Jan. 8, 2019) (Connecticut "adopts the approach of … *Holmes*" to "decide what's too indirect to sue over"). Noting the "many links" in the "causation chain" separating the defendants' alleged conduct from the cities' claimed injury, the court held that the plaintiff municipalities' allegations were "too attenuated to support a claim." *Id.* at *3–4.[14] Under settled West Virginia law and the undisputed facts, the same result is warranted here.

[13] *See also, e.g.*, *Harbaugh v. Coffinbarger*, 209 W.Va. 57, 543 S.E.2d 338, 345 (2000) (decedent's decision to play Russian roulette was "[a]n intervening cause ... making it and it only, the proximate cause of the injury" even though defendant had supplied the loaded gun); *Yourtee v. Hubbard*, 474 S.E.2d 613, 620 (W. Va. 1996) ("Generally a willful, malicious, or criminal act breaks the chain of causation."); *Bertovich v. Advanced Brands & Importing, Co.*, 2006 WL 2382273, at *11 (N.D. W.Va. Aug. 17, 2006) (holding that "illegal acts of third parties breaks the necessary chain of causation"); *Ashworth v. Albers Med., Inc.*, 410 F. Supp. 2d 471 (S.D. W.Va. 2005) (drug manufacturer not liable for injuries caused by alleged criminal acts of third parties introducing counterfeit versions of the manufacturer's drug into the stream of commerce).

[14] Those links include: "Link 1: The manufacturers make the opioids. Link 2: The manufacturers sell the opioids to the distributors. Link 3: The distributors sell the opioids to a pharmacy. Link 4: Doctors prescribe the opioids. Link 5: Patients take them. Link 6: Some patients become addicted. Link 7: The city must give emergency and social services to some addicts while the city's quality of life, property values and crime rate worsen from the spread of addiction, further straining city resources. … Link 8: Pills get loose and are sold on the black market creating other costly addicts. Link 9: Pills get too expensive or scarce for some addicts who turn to more accessible stocks of street fentanyl or heroin, creating costly addicts." *City of New Haven*, 2019 WL 423990 at *3.

II. PLAINTIFFS HAVE NO EVIDENCE TYING DEFENDANTS' CONDUCT TO THEIR ALLEGED INJURIES.

Plaintiffs lump three distinct sets of alleged injuries under the "opioid crisis" label: (1) harm flowing from legitimate opioid prescriptions written in good-faith by doctors pursuant to the then-prevailing standard of care, (2) harm flowing from illicit prescribing or dispensing of opioid medicines by "pill mill" doctors and rogue pharmacies, and (3) harm flowing from the use of illegal, non-prescription opioids, such as heroin and illicit fentanyl. Plaintiffs have failed to come forward with evidence that Defendants were the proximate cause of any of these categories of injury. For these separate and independent reasons, Defendants are entitled to summary judgment.

A. Legitimate Prescribing

According to Plaintiffs and their experts, the opioid crisis has its origin ***not*** in "pill mill" doctors or rogue pharmacies dispensing opioids in the absence of legitimate prescriptions,[15] but in prescriptions written by doctors for legitimate medical purposes.[16] As the DEA told Congress in 2014, over 99 percent of doctors adhere to the prevailing treatment guidelines and prescribe

[15] *See, e.g.*, Ex. 19 (Keyes MDL Rep.) at 18 ("'Pill Mills' do not explain in any significant way the expansion of opioid prescribing and opioid-related harm in the US."); Ex. 20 (Lembke MDL Rep.) at 12 ("[O]pioid overprescribing is not the result of a small subset of so-called 'pill mill' doctors … but rather has been driven by a wholesale shift in medical practice."); Ex. 13 (Lembke Rep.) at 24 ("[T]he increase in opioid prescribing is not explained by a minority of prolific prescribers alone. Rather, opioid prescribing has increased broadly across a variety of specialties.").

[16] *See, e.g.*, Third Amend. Compl. ¶ 15 ("This epidemic has been fueled and sustained by … a dramatic shift in how and when opioids are prescribed by the medical community and used by patients …."); Ex. 12 (Keyes Rep.) at 14 ("Opioid pain relievers became an increasingly widely-used option starting in the mid 1990s, particularly for chronic non-cancer pain, a use that had rarely been seen previously."); Ex. 13 (Lembke Rep.) at 20 ("Opioid prescribing began to increase in the 1980's and became prolific in the 1990's and the early part of the 21st century, representing a radical paradigm shift in the treatment of pain ….").

opioids appropriately.[17] And, during the relevant time-period, DEA (i) expressly endorsed treatment guidelines issued by the Federation of State Medical Boards that approved the use of opioids as a first-line treatment for chronic pain,[18] and (ii) approved a 39-fold increase in the opioid production quotas based on its determination that there was an increasing legitimate medical need for prescription opioids.[19] According to Plaintiffs' experts, it was pills dispensed pursuant to those lawful prescriptions that were subsequently diverted to an illegal, secondary market.[20]

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[17] Ex. 21 (Rannazzisi 2014 Testimony) at 76 ("I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing …."); Ex. 9 (71 Fed. Reg. 52,716) at 52,719 ("[T]he overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by Federal or State law enforcement officials.").

[18] Ex. 36 (DEA, Controlled Substances and Pain Management) (endorsing FSMB's guidelines as "consistent with … DEA's pain management position").

[19] DEA sets an aggregate production quota for controlled substances. *See* 21 U.S.C. § 826; 28 C.F.R. 0.100; *see also* Ex. 22 (Rannazzisi 2006 Testimony) at 68 ("[I]n the case of the most potentially dangerous drugs, in Schedule II … [DEA] control[s] the amount produced, bought, sold and otherwise transferred."). That quota represents the amount that DEA determines is needed "for the estimated medical, scientific, research, and industrial needs of the United States" during a given year. 21 U.S.C. § 826(a)(1). Based on its expert judgment that there was an increasing legitimate medical need for opioids throughout the United States, between 1993 and 2015, DEA authorized a 39-fold increase of the manufacturing quotas for prescription opioids. *See* Ex. 23 (07.11.17 Ltr. from Durbin to Rosenberg); Ex. 24 (Aggregate Production Quota History for Selected Substances 2000-2010); Ex. 25 (Aggregate Production Quota History for Selected Substances 2003-2013); Ex. 26 (Aggregate Production Quota History for Selected Substances 2009-2019); Ex. 27 (Rannazzisi MDL Dep.) at 31:8–10 (former head of the DEA's Office of Diversion Control testifying that quota levels for opioids "constantly increased" under his watch); *see also* Ex. 28 (2019 OIG Report) at 13 ("Yet, from 2003 to 2013, DEA authorized manufacturers to produce substantial amounts of opioids."). Defendants play no role in setting, advocating for or increasing DEA production quotas. *See, e.g.*, Ex. 29 (Harper-Avilla MDL Dep.) at 111:12–21, 112:9–13, 112:20–113:1.

[20] *See* Ex. 12 (Keyes Rep.) at 27 (opining that "the widespread availability of prescription opioids, often prescribed in extraordinarily high quantities … le[ft] a surplus of opioids that could be diverted for non-medical uses."). To the extent Plaintiffs claim harms resulting from the addiction or overdose of patients who were lawfully prescribed opioids by their doctors, that harm does not involve diversion and cannot be a source of liability *as to Defendants*. Wholesale distributors have no duty—and no ability—to prevent harms arising from the use of controlled substances by patients in accordance with good-faith prescriptions written by their doctors.

Plaintiffs contend that Defendants should have investigated and blocked some number of "suspicious orders." *See, e.g.*, Third Amend. Compl. ¶¶ 801–03. But there is no evidence that (i) any Defendant shipped opioids that were not ordered by a DEA-registered customer authorized to receive them, or (ii) any such customers ordered opioid medicines in excess of the volume needed to fill prescriptions written by State-licensed doctors. For purposes of causation, then, the question is whether any Defendant—if it had more carefully scrutinized or investigated the orders it received[21]—would have determined that the orders should not have shipped because they reflected inappropriate prescribing outside the prevailing standard of care. ***None*** of Plaintiffs' experts has even considered that question, let alone offered opinions sufficient to create a triable question of fact. And Plaintiffs have ***no evidence*** of any pharmacy orders that should have been flagged as "suspicious" because the underlying prescriptions were contrary to the prevailing standard of care.

Where legitimate prescribing is concerned, it is not the job of wholesale distributors, nor is it within their authority, to second-guess prescribing decisions of doctors or prevent patients from obtaining medicines prescribed in good faith by their doctors—as Plaintiffs' own diversion expert admits.[22] Accordingly, even if Defendants had the ability to review and investigate individual prescriptions (they do not), they would have had no basis to challenge any legitimate prescriptions written by State-licensed doctors. Moreover, even if Defendants had the ability and authority to challenge individual prescribing decisions (they have neither), there is ***no evidence***

[21] Defendants dispute that they owed a duty to Plaintiffs to scrutinize the orders they received from their DEA-registered customers.

[22] *See, e.g.*, Ex. 30 (Rafalski Dep.) at 112:18–113:16 ("Q. [T]he DEA doesn't expect distributors to make medical judgments about whether patients who have a valid prescription actually need that prescription; correct? A. I would agree with that statement, sir. Q. It's not the role of distributors to second guess legitimate medical prescribing … correct? A. I would generally agree ….").

that, had Defendants examined any prescriptions or groups of prescriptions under the prevailing treatment guidelines, they should have flagged any orders and refused to ship them.

The absence of such evidence is fatal to Plaintiffs' ability to establish proximate causation. Proof of causation requires (at a minimum) evidence that, had Defendants conducted adequate due diligence, the result would have been different—i.e., Defendants would have flagged a significant number of pharmacy orders, halted their shipment, and thereby reduced in a material way the volume of opioids shipped into Cabell County. While Plaintiffs' experts opine—***in retrospect*** based on the ***current*** standard of care—that many physicians over-prescribed opioids for chronic pain, none opines that hospitals or pharmacies within Cabell County placed an "excessive" number of orders ***under then-prevailing treatment guidelines***, or attempts to identify which orders (or even what portion of orders in the aggregate) were "suspicious" or "excessive" when viewed contemporaneously.

Plaintiffs' expert Craig McCann used algorithms provided by counsel to purportedly identify shipments that Defendants could have "flagged" for further due diligence. *See* Ex. 31 (McCann Rep.) ¶¶ 104–128. McCann, however, does not opine that (1) any of those algorithms could feasibly have been used to identify "suspicious" orders as they were received; (2) any of the "flagged" shipments were actually suspicious or medically inappropriate based on the ***then-prevailing treatment guidelines***; or (3) any of the "flagged" shipments were in fact diverted or harmed Plaintiffs. *See* Ex. 32 (McCann Dep.) at 14:1–15:4, 100:19–101:10, 127:14–128:5.

Similarly, while Plaintiffs' expert James Rafalski opines that one of the algorithms applied by Dr. McCann "provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size," Ex. 33 (Rafalski Rep.) at 50, he does not consider whether, or opine that, any order meeting this "initial trigger" for further due diligence was actually suspicious based on

the ***then-prevailing treatment guidelines*** or was ultimately diverted to illicit use.[23] To the contrary, Mr. Rafalski admits that he cannot identify the number of opioid pills that entered Cabell County unlawfully. *Id.*

While various Plaintiff experts opine that there is a correlation between opioid distribution and overdose deaths, that is not a causation opinion. Those experts, like Dr. McCann and Mr. Rafalski, make absolutely no effort to identify specific orders or groups of orders that Defendants should not have shipped and thus to quantify the amount of opioids that would not have reached Cabell County if Defendants had done adequate due diligence. Absent such evidence, there is no proof that Defendants' alleged wrongdoing caused Plaintiffs any harm.

In sum, there is no basis for holding Defendants liable where legitimate prescribing is concerned. Defendants have no ability and—under West Virginia law, no duty—to prevent patients from receiving medicines prescribed by their doctors in good faith and in accordance with the then-prevailing treatment guidelines. And this remains true even if, in hindsight, some number of those prescriptions turn out to have been "excessive" or medically unnecessary. Because Plaintiffs have no evidence establishing that additional "diligence" by Defendants could or should have prevented patients from receiving medicines prescribed in good faith by their doctors pursuant to the then-prevailing standard of care, Plaintiffs cannot establish that Defendants were a proximate cause of any harm flowing from such good-faith prescribing.

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[23] *See* Ex. 30 (Rafalski Dep.) at 87:21–88:2 ("Q. You've not reviewed each of those flagged orders; correct? A. No, sir. Q. Do you know how many of the tens of millions you've actually reviewed? A. Yes, I have not reviewed any of them."); 88:12–15 ("Q. Did you individually review any of [the flagged orders] to see if … you would consider it to be suspicious? A. No, sir."); 90:13–23 ("Q. Did you look at any of those tens of millions of orders in terms of the actual facts of those orders … you believe that order is likely to be diverted? A. I cannot definitively look at one specific order and tell you that specific order was diverted … I did not do that and I could not do that.").

B. Illicit Prescribing or Dispensing

As previously noted, Plaintiffs and their experts make clear that illicit prescribing and dispensing by doctors and pharmacies was ***not*** the primary contributor to the opioid epidemic. *See supra* Part II.A. In any event, to the extent "pill mill" doctors and rogue pharmacies are concerned, the record demonstrates that Defendants' purportedly wrongful shipments did not proximately cause Plaintiffs' injuries.

Plaintiffs have ***no evidence*** that Defendants made shipments they should not have made because of illicit prescribing or dispensing. Plaintiffs bear the burden of proving a direct connection between their claimed injuries and specific conduct on the part of Defendants—that is, specific, allegedly improper shipments. But the record does not establish any causal relationship between the opioid pills shipped by Defendants and Plaintiffs' alleged injuries from illegal prescribing by "pill mill" doctors or illicit dispensing of pills. Plaintiffs have not, for instance, identified any pharmacies that filled prescriptions written by "pill mill" doctors and demonstrated that they were harmed as a result of a Defendant's shipments to those pharmacies. Nor do Plaintiffs have any evidence that they incurred expense as a result of shipments to particular pharmacies in Cabell County that Defendants knew (or should have known) were dispensing prescription opioids without legitimate prescriptions.

Plaintiffs' experts do not fill this gap. Plaintiffs have no expert who attempts to show—in the aggregate or otherwise—that Defendants should have halted certain orders because they knew or should have known that the orders were the result of (i) improper prescribing by doctors (i.e., prescribing that was inconsistent with then-prevailing treatment guidelines) or (ii) were intended to fill anything other than bona fide prescriptions. Although one expert—Dr. Michael Siegel—purports to identify a small number of pharmacies that Defendants supplied in quantities "that were inconsistent with public health," Ex. 34 (Siegel Rep.) at 32–78, he does not (1) identify any specific

orders shipped by Defendants to those pharmacies that were subsequently diverted and caused Plaintiffs any harm, or (2) opine that any orders shipped by Defendants to those pharmacies were inappropriate or excessive ***in light of the prevailing standard of care at the time the orders were placed***. Dr. Siegel's identification of these pharmacies, standing alone, is not enough to create a triable question of fact.

Moreover, for the reasons described above, Plaintiffs have no evidence that Defendants' alleged conduct was a ***proximate*** cause of any injuries flowing from illicit prescribing or dispensing. *See supra* Part I. In every such case, Plaintiffs' alleged harm was more directly caused by (i) the doctors or pharmacists who made the independent decision knowingly to dispense or prescribe opioid medicines in the absence of a legitimate medical need, and (ii) the persons who used the medicines in the absence of a legitimate medical need.

C. Illegal, Non-Prescription Opioids

Plaintiffs' purported injuries stem in substantial part from the abuse of non-prescription opioids such as heroin and illicit fentanyl. *See, e.g.*, Third Amend. Compl. ¶¶ 9, 17, 22.[24] Insofar as Plaintiffs claim as injury future costs they will incur responding to use of illicit, non-prescription drugs by individuals in Cabell County, it is especially clear that Defendants are entitled to summary judgment.

[24] Especially in recent years, the use of illegal street drugs has been the major driver of Plaintiffs' opioid-related injury. *See* Ex. 13 (Lembke Rep.) at 163 ("We are now in the second and third waves of this epidemic, with a spike in deaths from illicit opioids, particularly heroin (second wave) and illicit fentanyl (third wave)."); Ex. 12 (Keyes Rep.) at 28, 32 (opining that "[t]here have been rapid increases in opioid overdose death due to heroin and synthetic opioids," that "[i]n recent years, heroin deaths have increased as being involved in overdose deaths" and that "[s]ynthetic opioid (e.g. fentanyl) deaths began exponentially increasing … in recent years as well"); Ex. 14 (Ciccarone Rep.) at 24 (detailing the second and third "waves" of heroin and synthetic opioid abuse).

Defendants do not supply illicit drugs, either directly or indirectly, to anyone. Rather, the evidence reflects that these drugs are trafficked into Cabell County by illicit drug trafficking organizations from China and Mexico.[25] If someone in Plaintiffs' jurisdictions overdoses on heroin (or another illegal street drug), and that overdose causes Plaintiffs to incur expense, Defendants did not supply those illegal drugs and cannot be the proximate cause of that expense.

Moreover, the causal chain separating Defendants' conduct from Plaintiffs' injury resulting from illegal drug use is especially remote. As an initial matter, Defendants did not proximately cause anyone in Cabell County to become dependent on prescription opioids in the first place. *See supra* Part I. Absent proof of that, Defendants are missing from the chain of causation leading from prescription drug use, to illicit drug use, and on to Plaintiffs' alleged injuries.

Even setting aside that threshold issue, the chain of causation separating Defendants' shipments of FDA-approved medicines from the illicit use of illegal street drugs (and attendant government expenditures) is too indirect and attenuated by subsequent criminal conduct. The actors and events standing between a person's use of lawfully prescribed medicines and Plaintiffs' claimed injuries include at least (1) the sale of an illegal drug by a dealer and (2) the unlawful purchase and use of the drug by someone in Cabell County. At a minimum, therefore, Defendants are entitled to summary judgment insofar as Plaintiffs' claimed injuries arise from the use of illicit, non-prescription opioids. *See, e.g.*, *Hemi Group, LLC v. City of New York, N.Y.*, 559 U.S. 1, 11

[25] *See* Ex. 35 (2017 National Drug Threat Assessment) at 45 ("Poppy cultivation and heroin production levels in Mexico, the primary source of heroin for the U.S. market, continues to increase."); *id*. at 65 ("Fentanyl is transported into the United States in parcel packages directly from China or from China through Canada. …"); *see also, e.g.*, Ex. 17 (Brown Dep.) at 38:5–17 ("Q. Do you know … what are the places of origin of the illegal fentanyl that you're seeing now? A. Just generally speaking, a large portion of it comes from China, shipped from China."); Ex. 15 (Cox Dep.) at 104:4–9 ("Q. What about … Mexican cartels, would they be a source of the illegal narcotics brought into the City of Huntington? A. I believe ultimately they would be the, you know, probably one of the main first-line suppliers of it, yes.").

(2010) (plurality opinion) (*Holmes* test not satisfied where alleged injury was contingent on intervening third-parties' decisions "not to pay taxes they were legally obligated to pay"); *City of Charleston*, 2020 WL 4116952, at *25 (*Holmes* test not satisfied where "[p]laintiffs' claims rely on various criminal actions of third parties, such as illegal drug trafficking").

CONCLUSION

Because there is no evidentiary basis on which a reasonable jury could conclude that Defendants proximately caused Plaintiffs' injuries, Defendants are entitled to summary judgment.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 22nd day of September, 2020, the foregoing "MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PROXIMATE CAUSATION GROUNDS" was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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